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**SIX-YEAR RESULTS OF COLLAGEN MENISCUS IMPLANTS EMPHASIZING LOCATION AND MENISCUS REMAINING**W.G. Rodkey<sup>1</sup>, K.K. Briggs<sup>1</sup>, J.R. Steadman<sup>2</sup><sup>1</sup>Steadman Hawkins Res. Fndn., Vail, CO; <sup>2</sup>Steadman Hawkins Clinic, Vail, CO

**Purpose:** Prospectively, we determined amount of meniscus loss and anatomic location of Collagen Meniscus Implant (CMI) placement after partial medial meniscectomy (PMM). At 1-year relook we determined total meniscus tissue present based on surface area coverage. We correlated percent of meniscus and anatomic location of the original lesion with function and activity levels 6 years after CMI placement. We hypothesized that meniscus amount and anatomic location would influence clinical function and activity levels.

**Methods:** In a prospective randomized controlled multicenter clinical trial (Level of Evidence I), 114 chronic patients (1 to 3 prior PMM on the involved meniscus) 18 to 60 years old underwent partial medial meniscectomy, and then randomly one group received a CMI to fill the meniscus defect. There were 68 PMM only controls and 46 CMI patients. At index surgery, amount and anatomic location of meniscus removed and CMI placement were documented on a standard grid. Locations were categorized as posterior (A), middle (B), or anterior (C) third. A 1-year relook was done on CMI patients, and meniscus surface area coverage was measured. Patients were followed clinically for a minimum of two years and subjectively annually thereafter. Average follow-up was 69 months (range, 24 to 92). All patients completed validated questionnaires including Lysholm and Tegner scores to assess function and activity.

**Results:** For CMI patients, 29 had lesions which included posterior and middle thirds (AB), and 17 had lesions involving all three zones (ABC). Lysholm scores were significantly higher in patients with AB lesions (81) compared to ABC lesions (71),  $p=0.046$ . AB lesion patients also had significantly higher Tegner index (0.70) than ABC lesion patients (0.22), thus AB patients regained more of their lost activity,  $p=0.049$ . Comparing all patients with  $\geq 60\%$  meniscus surface area coverage, CMI patients had significantly higher Tegner index compared to controls (0.59 vs. 0.30),  $p=0.036$ . No differences between treatment groups were seen in patients with  $<60\%$  meniscus surface area coverage. When comparing 24 month to final follow-up values, controls had no change for Lysholm ( $p=0.13$ ) or Tegner ( $p=0.39$ ) scores, but CMI patients improved significantly over time for both Lysholm ( $p=0.02$ ) and Tegner ( $p=0.04$ ) scores.

**Conclusions:** Zones of meniscus involvement influenced clinical outcomes at 6 years in CMI patients. Those whose lesions extended into all three zones did worse than those with lesions in posterior and middle zones only. Patients with successful CMI procedures yielding  $\geq 60\%$  meniscus surface area coverage were significantly better than PMM only controls for both clinical function and activity levels. Noteworthy, CMI patients continue to improve over time for clinical function and activity levels, but PMM controls do not.

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**ANATOMIC LOCATION OF PARTIAL MEDIAL MENISCECTOMY CORRELATES WITH TWO-YEAR FUNCTION AND ACTIVITY LEVELS**W.G. Rodkey<sup>1</sup>, K.K. Briggs<sup>1</sup>, J.R. Steadman<sup>2</sup><sup>1</sup>Steadman Hawkins Res. Fndn., Vail, CO; <sup>2</sup>Steadman Hawkins Clinic, Vail, CO

**Purpose:** Prospectively, we determined the anatomic loca-

tion of partial medial meniscectomy and then correlated the anatomic location with function and activity levels two years post-meniscectomy. We hypothesized that loss of the posterior third of the medial meniscus would result in more compromised clinical function and activity levels than loss of the middle or anterior third.

**Methods:** In a prospective randomized controlled multicenter clinical trial (Level of Evidence I), 120 patients (18 to 60 years) underwent partial medial meniscectomy and served as controls. There were 74 acute (no prior meniscus surgery) and 46 chronic (1 to 3 prior partial meniscectomies on the involved meniscus) patients. At index surgery, the anatomic location of meniscus removed was documented on a standard grid. Locations were categorized as posterior, middle, or anterior third. Patients were followed clinically for a minimum of two years after meniscectomy. All patients completed validated questionnaires including Lysholm and Tegner scores to assess function and activity.

**Results:** Seventeen (17) patients had isolated posterior third meniscectomies, 83 had combined posterior/middle thirds, 10 had isolated anterior, and 10 had combined anterior/middle/posterior thirds partial meniscectomies. Patients with isolated posterior third meniscectomies had significantly lower Lysholm scores (78) compared to all other patients (88) ( $p=0.01$ ) and also had significantly lower Tegner scores (3.5) compared to all other patients (4.5) ( $p=0.03$ ) at a minimum of two years after the index partial meniscectomy. Based on actual measurements, the isolated posterior third meniscectomy group had an average of 41% meniscus removed, well below the 50% loss threshold level that has been previously reported as a predictor of decreased function and activity levels.

**Conclusions:** Function and activity levels were significantly decreased two years after surgery in patients who had isolated posterior third medial meniscectomies compared to all other patients with meniscus loss in other anatomic locations of the medial meniscus. This decrement of function and activity occurred even though less than 50% of the meniscus was removed. This study confirms the importance of preserving the posterior portion of the meniscus. It also supports the potential positive benefits that may be achieved by replacing or regrowing lost meniscus tissue. Our hypothesis was affirmed.

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**EVALUATIONS OF AVASCULAR MENISCAL REPAIR WITH A NOVEL CONDUIT MANUFACTURED FROM VARIOUS BIOABSORBABLE MATERIALS**M. Long<sup>1</sup>, F. Proch<sup>2</sup>, R. Zhang<sup>1</sup>, M.F. Koff<sup>3</sup>, L. Foo<sup>3</sup>, J. Campbell<sup>2</sup>, H. Potter<sup>3</sup>, H. Schwartz<sup>2</sup><sup>1</sup>Stryker Joint Preservation, Mahwah, NJ; <sup>2</sup>Schwartz BioMed., Fort Wayne, IN; <sup>3</sup>Hosp. for Special Surgery, New York, NY

**Purpose:** Meniscus repair is dependent on the initial mechanical fixation, stability of the tear and the regional biological repair mechanisms largely dependent on establishing vascularity at the tear site. The placement of a conduit (BioDuct<sup>®</sup>) between the vascular bed of the meniscus or the vascularized synovium/capsule has shown promise in repairing tears in less vascularized zones. This study aimed to compare various bioabsorbable polymer materials to assess i) the biomechanical and degradation characteristics after in vitro simulation and ii) the biomechanical, histological and MRI characteristics of repair tissue using the canine avascular tear model.

**Methods:** The study devices were manufactured from bioabsorbable PLLA/PGA (%/%) materials: 100/0, 85/15, 50/50, 10/90, and sterilized via gamma irradiation. In vitro degradation was performed over 12 weeks according to ASTM standard F-1635-04a, with characterization by weight loss and mechanical properties ( $n=6$ ) and inherent viscosity measurements ( $n=3$ ). In the in vivo

adult dog model, two 5-mm longitudinal tears were created in the avascular portion of the medial meniscus. Each tear was treated with one BioDuct® implant placed at the tear site (n=10), followed by suture repair. After 16 weeks, both knees were assessed for gross pathology, articular cartilage damage (India ink staining), and repair tissue appearance. Limbs were processed for 3T MRI and histologic examination (n=4) or biomechanical evaluation (n=6). MRI evaluation utilized a water-sensitive, moderate echo time fast spin echo protocol previously applied clinically, with a resolution of 175  $\mu$ m by 187.5  $\mu$ m by 1.2 mm. Meniscal healing was made based on the presence or absence of fluid inhibition into the repair site as well as any discernible fragmentation.

**Results:** In vitro, the PLLA and 85/15 materials did not lose mass throughout the study. The 50/50 and 10/90 samples began to lose mass after 3 and 1 week, respectively and were almost completely degraded by 7 weeks. The inherent viscosity of the materials decreased more rapidly with increasing PGA content. The 3-point bend and crush strength properties of the implants were found to decrease with time, with the exception of PLLA.

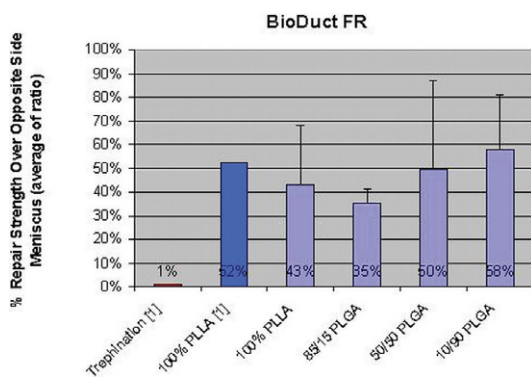


Figure 1. Biomechanical strength of repaired tear.

In vivo, all of the BioDuct® implant groups provided functionally healed avascular meniscal tissue in the dogs, independent of bioabsorbable polymer tested. Tear strengths of the repaired avascular tissue acquired 35-58% of contralateral, unoperated tissue (Fig. 1). Histological analysis showed evidence of tissue ingrowth and guided tissue engineering through the lumen of the conduit (Fig. 2). MRI analyses confirmed healing in 6 out of 8 anterior repairs and 7 out of 8 posterior repairs where the conduit was used (Fig. 3). Mild to moderate synovitis and chondral defects not necessarily associated with the use of the implant were observed with MRI; however, these defects were not apparent at gross necropsy via India ink staining.



Figure 2. Denovo tissue in BioDuct conduit lumen.

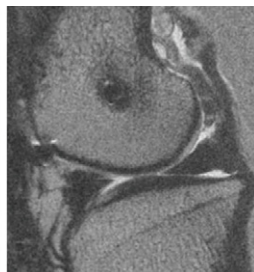


Figure 3. Sagittal fast spin echo MR demonstrates lack of fluid inhibition, suggesting healing.

**Conclusions:** This study demonstrated the success of BioDuct® repair in enabling healing of avascular tear in a dog meniscus, independent of the PLA/PGA materials tested.

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### SPECIFIC FACTORS ARE ASSOCIATED WITH FAILURE OF MENISCUS SUTURE REPAIR

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**Purpose:** Meniscus repairs with sutures have become more common as the importance of preserving the meniscus has been established. Studies have shown a high rate of repeat surgery, but it is unclear what factors contribute to failure. The purpose of this study was to determine what factors lead to failure of suture meniscus repair. Failure was operationally defined as repeat surgery on the meniscus within 2 years of the repair.

**Methods:** Two hundred eighty-three (283) meniscus suture repairs were performed by a single surgeon. The average patient age was 31 years (range, 18 to 71). There were 177 males and 106 females. All repairs were completed with an inside-out suture technique. One hundred thirty-seven (137) had an ACL reconstruction and meniscus repair (93 concurrent reconstructions and 44 two-staged ACL reconstructions). One hundred eighty-one (181) medial menisci and 102 lateral menisci were repaired. Of the medial repairs, 80% were in the posterior third of the meniscus, 11% in the middle third, 1% in the anterior third, and 8% extended to all areas of the meniscus. Of the lateral meniscus repairs, 49% were in the posterior third, 26% in the middle third, 22% in the anterior third, and 3% extended to all areas.

**Results:** Twenty-eight (28) patients (10%) had required repeat surgery on the repaired meniscus within the first 2 years and were considered failures. The average time to repeat meniscus surgery was 12 months (range, 2.5 to 24 months). There were no differences based on age, gender or location. Thirteen percent (13%) of medial repairs and 4% of lateral repairs failed (p=0.012). Medial meniscus repairs failed significantly earlier (5.6 months) than lateral meniscus repairs (12.9 months) (p=0.001). For patients who had ACL reconstruction and meniscus repair, factors associated with failure included age (failed age=22; non-failure age=29; p=0.013), and concurrent ACL reconstruction (two-staged repair failures=2%; concurrent repair failures=11%; p=0.04).

**Conclusions:** Failure of suture repair of the meniscus within the first two years following index repair is more likely to occur in medial meniscus repairs and in young patients who had a repair and concurrent ACL reconstruction.

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### USING A CULTURE MODEL OF HUMAN TENOCYTES TO INVESTIGATE THE EFFECTIVENESS OF TENDOACTIVE® FOR THE PROPHYLAXIS AND TREATMENT OF TENDINOPATHIES

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**Purpose:** Tendons have a limited capacity for self-repair due to low cell density and little mitotic activity. Pro-inflammatory cytokines such as interleukin-1 $\beta$  (IL-1 $\beta$ ) have been identified as the main initiators of tendinopathies, stimulating inflammation, apoptosis and extracellular matrix (ECM) degradation. The aim of this study was to evaluate the potential of Tendoactive®, a nutraceutical formulation that contains mucopolysaccharides, hydrolyzed type I collagen and vitamin C, in an *in vitro* model of tendon inflammation.

**Methods:** In monolayer cultures, primary human tenocytes were either treated with Tendoactive®, non-stimulated or stimulated with